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Proposed Re-evaluation Decision

PRVD2014-05

# Flumetsulam

(publié aussi en français)

**27 June 2014**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications  
Pest Management Regulatory Agency  
Health Canada  
2720 Riverside Drive  
A.L. 6604-E2  
Ottawa, Ontario K1A 0K9

Internet: [pmra.publications@hc-sc.gc.ca](mailto:pmra.publications@hc-sc.gc.ca)  
[healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra)  
Facsimile: 613-736-3758  
Information Service:  
1-800-267-6315 or 613-736-3799  
[pmra.infoserv@hc-sc.gc.ca](mailto:pmra.infoserv@hc-sc.gc.ca)

**Canada**

ISSN: 1925-0959 (print)  
1925-0967 (online)

Catalogue number: H113-27/2014-5E (print)  
H113-27/2014-5E-PDF (PDF version)

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## **Overview**

### **What Is the Proposed Re-evaluation Decision?**

After a re-evaluation of the herbicide flumetsulam, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing flumetsulam for sale and use in Canada.

An evaluation of available scientific information found that products containing flumetsulam do not present unacceptable risks to human health or the environment when used according to the proposed label directions. As a condition of the continued registration of flumetsulam uses, new risk reduction measures are proposed for the end-use product registered in Canada. No additional data are being requested at this time.

This proposal affects the products containing flumetsulam registered in Canada. Once the final re-evaluation decision is made, the registrant will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document<sup>1</sup> that summarizes the science evaluation for flumetsulam and presents the reasons for the proposed re-evaluation decision. It also proposes new risk reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of flumetsulam.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

### **What Does Health Canada Consider When Making a Re-evaluation Decision?**

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, presents the details of the cyclical re-evaluation approach which is in line with the requirements of the *Pest Control Products Act*.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

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<sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

## **What Is Flumetsulam?**

Flumetsulam is a selective herbicide which belongs to the triazolopyrimidine family and is classified as a Group 2 herbicide. Flumetsulam is an inhibitor of the plant enzyme acetolactate synthase. In Canada, it is currently registered for control of broadleaved weeds in hybrid field corn and soybeans in Eastern Canada only. Flumetsulam is applied by ground equipment only.

## **Health Considerations**

### **Can Approved Uses of Flumetsulam Affect Human Health?**

**Flumetsulam is unlikely to affect your health when used according to the proposed label directions.**

People could be exposed to flumetsulam by consuming food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Flumetsulam is unlikely to affect human health provided that risk-reduction measures proposed by the PMRA to further protect workers who handle the product are implemented.

## **Environmental Considerations**

### **What Happens When Flumetsulam Is Introduced Into the Environment?**

**Flumetsulam poses a potential risk to terrestrial and aquatic plants, therefore additional risk reduction measures need to be observed.**

When flumetsulam is released into the environment, some of it can be found in soil and surface water. In the terrestrial environment, flumetsulam is expected to be non-persistent to moderately persistent; no major transformation products are produced in soil. Flumetsulam is shown to bind weakly to soils and may have the potential to leach into groundwater, particularly in well drained, low organic matter soil.

In aquatic environments, flumetsulam is expected to be persistent; no major transformation products are produced in water under aerobic conditions. Under anaerobic conditions, flumetsulam is shown to transform to a single major product, reduced flumetsulam-hydrate which is expected to be persistent. In aquatic environments, flumetsulam and reduced flumetsulam-hydrate are expected to remain in the water phase with very little partitioning to sediments. Flumetsulam residues are not expected in the air because of its low volatility and it has a low potential for bioaccumulation in biota.

Flumetsulam may pose a risk to terrestrial and aquatic organisms. In order to minimize the potential exposure of aquatic organisms to flumetsulam, an unsprayed area (spray buffer zone) is needed between the sprayer and downwind sensitive habitats. The width of these spray buffer zones will be specified on the product label.

## **Proposed Measures to Minimize Risk**

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of flumetsulam, the PMRA is proposing further risk-reduction measures for product labels:

### **Human Health**

- Additional precaution statements to protect workers during handling of the product and bystanders from spray drift are required;
- A restricted-entry interval (REI) of 12 hours to protect workers entering treated sites is required; and
- A pre-harvest interval (PHI) of 90 days for soybean is required.

### **Environment**

- Precautionary statements and spray buffer zones for non-target aquatic habitats are required; and
- To reduce the potential for run off of flumetsulam to adjacent aquatic habitats, precautionary statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted are required.

Residues of flumetsulam have a high potential to leach, therefore, a label statement is required advising that flumetsulam has the potential to reach groundwater, particularly in areas where soils are permeable and/or the depth to the water table is shallow.

A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

## **Next Steps**

Before making a final re-evaluation decision on flumetsulam, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision<sup>2</sup> that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

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<sup>2</sup> "Decision statement" as required by subsection 28(5) of the Pest Control Products Act.



## Science Evaluation

### 1.0 Introduction

Flumetsulam is a selective herbicide that acts by inhibiting plant enzyme acetolactate synthase. This active ingredient belongs to the triazolopyrimidine family and is classified as a Group 2 herbicide.

Following the re-evaluation announcement for flumetsulam, the registrant of the technical grade active ingredient in Canada indicated continued support for all uses included on the label of the commercial class end-use products currently registered in Canada.

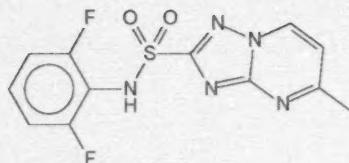
Currently registered products containing flumetsulam are listed in Appendix I. All current uses are being supported by the registrant and were, therefore, considered in the re-evaluation of flumetsulam.

The purpose of this re-evaluation is to review existing information on the active ingredient, flumetsulam, and the currently registered flumetsulam technical and commercial class end-use products, to ensure that previous risk assessments meet current standards.

### 2.0 The Technical Grade Active Ingredient, Its Properties and Uses

#### 2.1 Identity of the Technical Grade Active Ingredient

|  |  |
|--|--|
| <b>Common name</b>   | Flumetsulam  |
| <b>Function</b>  | Herbicide  |
| <b>Chemical family</b>   | Triazolopyrimidine   |
| <b>Chemical name</b>   |  |
| <b>1 International Union of Pure and Applied Chemistry (IUPAC)</b> | 2',6'-difluoro-5-methyl[1,2,4]triazolo[1,5- <i>a</i> ]pyrimidine-2-sulfonanilide               |
| <b>2 Chemical Abstracts Service (CAS)</b>                          | <i>N</i> -(2,6-difluorophenyl)-5-methyl[1,2,4]triazolo[1,5- <i>a</i> ]pyrimidine-2-sulfonamide |
| <b>CAS Registry Number</b>   | 98967-40-9   |
| <b>Molecular formula</b>   | C <sub>12</sub> H <sub>9</sub> F <sub>2</sub> N <sub>5</sub> O <sub>2</sub> S                  |

**Structural formula**

**Molecular weight** 325.3

**Registration Number** 24449

**Purity of the technical grade active ingredient** 98.0% nominal

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including Toxic Substances Management Policy (TSMP) Track 1 substances, are not expected to be present in the product.

## 2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

| Property  | Result  |
|---|---|
| Vapour pressure at 25°C                               | $3.7 \times 10^{-7}$ mPa  |
| Ultraviolet (UV) / visible spectrum                   | Acid Media (0.08 N HCl)<br>$\lambda = 213.3 \text{ nm } \epsilon = 3.80 \times 10^4 \text{ M}^{-1} \text{ cm}^{-1}$<br>$\lambda = 268.1 \text{ nm } \epsilon = 6.36 \times 10^3 \text{ M}^{-1} \text{ cm}^{-1}$<br><br>Neutral media (Milli-Q water)<br>$\lambda = 210.6 \text{ nm } \epsilon = 3.88 \times 10^4 \text{ M}^{-1} \text{ cm}^{-1}$<br>$\lambda = 275.9 \text{ nm } \epsilon = 6.52 \times 10^3 \text{ M}^{-1} \text{ cm}^{-1}$<br><br>Basic Media (0.08 N NaOH)<br>$\lambda = 277.2 \text{ nm } \epsilon = 7.02 \times 10^3 \text{ M}^{-1} \text{ cm}^{-1}$<br><br>No observed absorbance above 320 nm. |
| Solubility in water at 25°C                           | pH Solubility (g/L)<br>2.5 0.049<br>7.0 5.65  |
| <i>n</i> -Octanol/water partition coefficient at 25°C | $\text{Log } K_{ow} = -0.68; K_{ow} = 0.21$   |
| Dissociation constant                                 | $\text{pK}_a = 4.6$   |

## 2.3 Description of Registered Flumetsulam Uses

Flumetsulam is currently registered for use as a selective herbicide for the control of broadleaved weeds in hybrid field corn and soybeans in Eastern Canada only. Flumetsulam is registered for one application per growing season with an application rate ranging from 50 to 70 g a.i./ha. It is applied by ground equipment only.

### **3.0 Impact on Human and Animal Health**

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Occupational exposure to flumetsulam may occur while working as a mixer/loader/applicator or by entering treated sites.

When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

#### **3.1 Toxicology Summary**

Flumetsulam is rapidly absorbed and excreted with little degradation and no bioaccumulation after oral administration in rats.

Flumetsulam has low oral and dermal toxicity and slight toxicity via the inhalation route. Flumetsulam is non-irritating to the skin and minimally irritating to the eyes. Flumetsulam is not a skin sensitizer. The following warning statements are required on the label of the technical product: "CAUTION-POISON" and "Harmful if inhaled".

Following repeated short- and long-term oral dosing in several species, the most common finding was renal toxicity based on kidney lesions and associated effects in clinical chemistry and urinalysis. Chronic toxicity in mice and rats resulted in renal effects at the highest dose tested; however, flumetsulam was not determined to be oncogenic. Repeated short-term (21-day) dermal application of flumetsulam to rabbits resulted in no evidence of treatment-related systemic toxicity at doses up to 1000 mg/kg bw/day.

There was no evidence of mutagenicity or genotoxicity. There were no reproductive or developmental concerns identified for flumetsulam.

Appendix II provides an overview of flumetsulam toxicological endpoints used by the PMRA in human health risk assessments.

### **3.2 Pest Control Products Act Hazard Consideration**

The *Pest Control Products Act* factor was not established as part of this assessment and is therefore not incorporated into the quantitative risk assessment.

The database contains the full complement of required studies, including developmental toxicity studies in rats and rabbits, and a multi-generational toxicity study in rats.

Increased susceptibility of fetuses following in utero exposure, relative to the dams, was not observed in rat reproduction or ranc and rabbit developmental toxicity studies. No malformations occurred at any dose in the examined studies.

Based on the information above, a qualitative assessment of the toxicity database suggests that the potential risks to sensitive subpopulations and the reliability of the scientific data are accounted for by the current assessment.

### **3.3 Occupational Exposure**

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

Workers can be exposed to flumetsulam through mixing, loading or applying the herbicide or when entering a treated site to conduct activities such as scouting and/or handling treated crops.

#### **3.3.1 Mixer/Loader/Applicator Exposure and Risk**

Based on the currently registered flumetsulam use pattern, exposure to flumetsulam is expected to be mainly via dermal and inhalation routes for handlers. Exposure duration is expected to be short- to intermediate-term duration. The following exposure scenarios were identified:

- Mixing and loading of solutions and application using an open-cab groundboom sprayer;
- Mixing and loading of wettable granules and application using an open-cab groundboom sprayer; and
- Mixing and loading of wettable granules packaged in water-soluble packaging and application using an open-cab groundboom sprayer.

A quantitative assessment for mixing/loading of liquid formulations and groundboom application was previously conducted by the PMRA. The combined dermal plus inhalation exposure for workers wearing single layer clothing and gloves during mixing/loading, and single layer clothing (no gloves) during application was not of concern (MOE = 160,000; target MOE = 100). The exposure assessment for the solution formulation scenario was expected to be sufficient to encompass the wettable granule formulation.

Although certain default values have been revised since the previous PMRA assessment, the previous assessment provides sufficient protection to account for these differences. It is concluded that there are no occupational handler concerns with respect to flumetsulam products under current conditions of use.

### **3.3.2 Postapplication Exposure and Risk**

Based on the currently registered use-pattern, flumetsulam products are applied preplant, pre-emergence, or early post-emergence. Due to the early application timing, postapplication exposure to workers re-entering treated fields for the purpose of scouting, irrigation and hand weeding is expected to be minimal.

A flumetsulam postapplication exposure assessment was previously conducted by the PMRA for workers entering treated corn fields. Postapplication exposure was not of concern on the day of application (MOE = 9000, target MOE = 100).

Although certain default values have changed since the original assessment, the estimated MOE still provides sufficient protection to account for these differences. The assessment is considered adequate and it is concluded that there are no concerns with respect to postapplication exposure for workers.

The standard 12-hour restricted-entry interval (REI) is proposed based on current PMRA practices. The proposed label statements are listed in Appendix V.

## **3.4 Non-occupational Exposure**

### **3.4.1 Residential Exposure and Risk**

There are no residential uses of flumetsulam in Canada. Bystander exposure is expected to be minimal and limited to exposure from drift. Certain labels contain statements pertaining to drift. A standardized statement should be added to all the labels to specify that application is limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

### **3.4.2 Dietary Exposure and Risk**

Flumetsulam is registered in Canada for use on hybrid field corn and soybean. Canadian MRLs are established at 0.05 ppm for soybean (dry) and field corn.

The flumetsulam acceptable daily intake (ADI) is 1.0 mg/kg bw/day based on a no observed effect level (NOEL) of 100 mg/kg bw/day from a one-year oral study in the dog and a composite assessment factor of 100. No acute dietary exposure assessment or cancer dietary exposure assessment is required for flumetsulam.

A flumetsulam chronic dietary exposure assessment (DEA) was previously conducted by the PMRA using the Dietary Exposure Evaluation Model (DEEM<sup>TM</sup>, version 7.075) which incorporated consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals. The assessment included soybean, corn and animal commodities.

Chronic dietary exposure (from food only) was less than 0.5% of the ADI for all population subgroups. The highest exposed population subgroup was non-nursing infants. The exposure estimate from drinking water, based on newly available data, is less than the estimate used in the previous DEA. Therefore an updated dietary risk assessment is not required. In conclusion, exposure from food and drinking water was also below the level of concern.

The large margin between the reference dose and the exposure estimate calculated in the assessment is expected to be protective of flumetsulam residues in domestic and imported foods. As there is currently no preharvest interval (PHI) for soybean, a PHI of 90 days is proposed. The 90-day PHI is consistent with that of field corn and is supported by the available Canadian soybean residue data.

### **3.4.3 Aggregate Exposure and Risk**

Aggregate risk combines the different routes of exposure to flumetsulam (for example, from food, water and residential exposures). Residential exposure to flumetsulam is expected to be negligible. Therefore, aggregate exposure is limited to exposure from food and drinking water. Based on the flumetsulam dietary exposure assessment, aggregate dietary exposure from food and drinking water is not of concern.

### **3.5 Cumulative Exposure and Risk**

A common mechanism of action has not been found for flumetsulam and other pesticide products, nor is this active ingredient considered to produce a metabolite common to other pesticide active ingredients. Therefore, a cumulative risk assessment is not required.

## **4.0 Impact on the Environment**

### **4.1 Fate and Behaviour in the Environment**

Flumetsulam enters the terrestrial environment when it is used as a herbicide on corn and soybean. Based on its physical properties, flumetsulam is highly soluble in water and has a low potential to volatilize from moist soil or water surfaces (Henry's law constant =  $7.571 \times 10^{-9}$  atm m<sup>3</sup>/mol). Hydrolysis and photolysis (in soil and water) are not considered to be important routes of transformation for flumetsulam in the environment.

In the terrestrial environment, flumetsulam is expected to be non-persistent to moderately persistent under aerobic conditions ( $DT_{50} = 12.4 - 150$  days). Aerobic biotransformation is shown to be more rapid at higher pH and lower organic carbon. No transformation products above 10% of applied radioactivity were identified in aerobic soil. Adsorption data indicate that flumetsulam is highly mobile in soils ( $K_{oc} = 4 - 15$ ); the results of a laboratory leaching study

show that flumetsulam residues are capable of leaching through soil. The leaching assessment using Groundwater Ubiquity Score (GUS) indicates that flumetsulam will leach in soil and satisfies most of the criteria of Cohen et al. 1984 (PMRA#1918520). In Canadian terrestrial field dissipation studies, flumetsulam residues were not detected beyond 15 cm soil depth. However, in American terrestrial field dissipation studies done in relevant ecoregions, flumetsulam residues are shown to move up to 120 cm in small amounts in well drained, low organic matter soil when rain falls shortly after application. Currently there is no available groundwater monitoring data for flumetsulam in Canada, however, in the U.S.A. flumetsulam residues have been detected in groundwater. Flumetsulam residues have been detected in surface water in Canada (Appendix IV).

In aquatic environments, flumetsulam is expected to be persistent under aerobic conditions and to remain in the water phase with very little partitioning to sediments. No major transformation products were identified in a laboratory aerobic aquatic biotransformation study that was conducted for a short duration (56 days). Under anaerobic conditions, flumetsulam transformed to a single major product, reduced flumetsulam-hydrate, which preferentially partitions to the water phase. Both flumetsulam and reduced flumetsulam-hydrate are expected to be persistent under anaerobic conditions.

The log octanol/water partitioning coefficient for flumetsulam ( $K_{ow} = 0.21$ ) suggests that it will not bioaccumulate in the food chain. Environmental fate data for flumetsulam and its transformation products, in the terrestrial and aquatic environment, are summarized in Table 1 and 2 of Appendix III, respectively.

#### **4.2 Environmental Exposure and Risk Assessment**

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Expected environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the RQ is then compared to the level of concern (LOC). If the screening level RQ is below the level of

concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

#### **4.2.1 Risks to Terrestrial Organisms**

A risk assessment of flumetsulam to terrestrial organisms was based upon an evaluation of toxicity data for the following:

- one earthworm species (acute exposure)
- one bee species (acute exposure)
- two bird species (acute, reproduction exposure)
- one mammal species (acute, reproduction exposure)
- twelve plant species (seedling emergence and vegetative vigor)

A summary of terrestrial toxicity data for flumetsulam is presented in Appendix III, Table 3. For the assessment of risk, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with flumetsulam.

##### **Terrestrial Invertebrates**

The screening level risk assessment for terrestrial invertebrates is summarized in Appendix III, Table 4. Earthworms are at negligible risk of ecological effects from exposure to flumetsulam as the RQs are several orders of magnitude lower than the level of concern ( $RQ = < 0.00003$  for acute effects). For acute contact toxicity to bees the  $LD_{50}$  is  $> 100 \mu\text{g a.i./bee}$ , equivalent to 112 kg a.i./ha. This value is approximately 1600 times the maximum single application rate for flumetsulam (70 g a.i./ha), therefore, there is a negligible risk of acute adverse effects to honey bees due to exposure to flumetsulam.

##### **Terrestrial Plants**

Non-target plants could be exposed to flumetsulam by overspray and spray drift. The risk to non-target plants was assessed based on an  $EC_{25}$  of 0.1 g a.i./ha based on reduced vegetative vigour for rape (reduced shoot length). At the maximum single seasonal rate of 70 g a.i./ha, the RQ ( $EEC/EC_{25} = 700$ ) greatly exceeds the PMRA's level of concern.

An EEC for flumetsulam resulting from spray drift was estimated based on the maximum percentage rate (% spray drift) that will drift from the application site during spraying onto areas 1 m downwind from the edge of the spray swath. The percent drift expected from the use of groundboom sprayer equipment using a coarse ASAE (American Society of Agricultural Engineers) droplet size, is 3%. At the maximum seasonal crop application rate of 70 g a.i./ha, the RQs for spray drift (EEC/EC<sub>25</sub> = 21) exceeds the LOC. This screening assessment triggers the calculation of buffer zones in order to protect non-target plants from spray drift.

### **Terrestrial vertebrates**

Wild birds and mammals may be exposed to residues of flumetsulam as a result of sprayed vegetation and/or contaminated prey. Standard exposure scenarios on vegetation and other food sources based on correlations in Hoerger and Kenaga (1972) (PMRA#1918526) and Kenaga (1973) (PMRA#1918527) and modified according to Fletcher et al. (1994) (PMRA#1918522) were used to determine the concentration of pesticide in the diet of small wild birds and mammals. Exposure is dependent on the body weight of the organism and the amount and type of food consumed. In the screening level assessment a set of generic body weights was used for birds and mammals (20, 100 and 1000 g, and 15, 35, 1000 g, respectively) to represent a range of small wild bird and small mammal species. It is noted that diets of animals can be highly variable from season to season as well as day to day. Furthermore, animals are often opportunists and if they encounter an abundant and/or desirable food source, they may consume large quantities of that food. For these reasons, the screening level assessment uses relevant food categories or feeding guilds for each size group consisting of 100% of a particular dietary item. At the screening level, only one feeding guild for each category of bird and mammal weights is selected. The selected feeding guilds are relevant to each specific size of bird or mammal and based on the most conservative residue values (maximum residues determined in the Hoeger and Kenaga nomogram). A diet consisting of 100% plant material is not considered realistic for small and medium sized birds (20 and 100 g) and small mammals (15 g) and, therefore, was not included in the determination of estimated daily exposures (EDEs). The most conservative exposure estimate for these categories of bird and mammal weights is associated with a diet comprised of 100% small insects.

The “leaves and leafy crops” category of the nomogram is associated with the highest exposure estimate in the assessment (300 mg a.i./kg dw diet). This category of vegetation is defined by plants with very high moisture content (comparable to lettuce and cabbage). It is very unlikely that the diets of birds and mammals would be made up of an important proportion of this food item as these do not contain sufficient nutrients to meet their daily energy requirements. Large birds are not known to purposely feed on lettuce-type crops; only some incidental ingestion has been noted when birds are feeding on insect pests on the crop; birds may also feed on young shoots of various types of crop, which would be more similar to grass-like vegetation or forage crops. For large birds (1000 g), exclusive feeding on short grass is the most conservative scenario. It is thought to be possible that small herbivorous mammals would feed on leaves and leafy crops in some situations; even though these crops may not meet all the energy requirements of a small mammal, these represent an abundant and easily accessible source of food. Flumetsulam is applied to corn and soybean, crops that are not relevant to the leafy foliage category (for example, lettuce-type crops).

Therefore, the short grass category of the nomogram, the next most conservative scenario, was chosen for medium- and large-sized mammals (35 and 1000 g).

The calculated screening level risk quotients for birds and mammals are shown in Table 5 and 6 of Appendix III, respectively. The LOC was not exceeded for birds and small wild mammals based on acute and reproductive endpoints. Flumetsulam, therefore, is expected to pose a negligible acute and reproductive risk to birds or mammals.

#### 4.2.2 Risks to Aquatic Organisms

A risk assessment for flumetsulam to aquatic organisms was based upon an evaluation of toxicity data for the following:

- one freshwater invertebrate species (acute and chronic exposure)
- three freshwater fish species (acute and chronic exposure)
- three freshwater algae species (acute exposure)
- one freshwater vascular plant species (acute exposure)
- two estuarine/marine invertebrate species (acute exposure)
- one estuarine/marine fish species (acute exposure)
- one estuarine marine algae species (acute exposure)

A summary of aquatic toxicity data for flumetsulam is presented in Table 3 (Appendix III).

#### Screening Level Assessment

Aquatic organisms can be exposed to flumetsulam as a result of spray drift and run-off. To assess the potential for effects from exposure to flumetsulam, screening level EECs in the aquatic environment based on direct application to water were used as exposure estimates. The calculated EECs were those determined in 15 cm body of water for amphibians and 80 cm body of water for all other aquatic organisms.

Detailed screening level assessments of the risk from flumetsulam to aquatic organisms are summarized in Table 7, Appendix III. Toxicity endpoints for most aquatic species were several orders of magnitude higher than the screening level EECs with the exception of those for aquatic plants and algae; RQs for aquatic plants and algae exceed the LOC (RQ = 3.5).

The risk to freshwater aquatic vascular plants and algae was further characterized by taking into consideration the concentrations of flumetsulam that could be deposited in off-field aquatic habitats that are downwind and directly adjacent to the treated field through drift of spray. The spray drift data of Wolf and Caldwell (2001) was used to determine that the maximum spray deposit into an aquatic habitat located 1 metre downwind from a treated field. The maximum amount of spray that is expected to drift 1 m downwind from the application site during spraying using field sprayer equipment and a coarse spray droplet size is 3%. Using this percentage for off-site drift to non-target aquatic habitats, the offsite EEC for flumetsulam at the maximum application rate (70 g a.i./ha) is expected to be 0.26 µg/L for a water body of 80 cm depth; the LOC is not exceeded for aquatic vascular plants and algae (RQ = 0.26/ 2.5 = 0.1). Spray drift of flumetsulam, therefore, is not expected to pose a risk to these aquatic organisms.

#### **4.2.3 Summary**

Available environmental studies suggest that in the natural environment, flumetsulam is slightly to moderately persistent in soil and persistent in water. No major transformation products are produced in soil or water under aerobic conditions; under anaerobic conditions, flumetsulam is shown to transform to a single major product, reduced flumetsulam-hydrate which is expected to be persistent. In aquatic environments, flumetsulam and reduced flumetsulam-hydrate are expected to remain in the water phase with very little partitioning to sediments. Flumetsulam has the potential to leach through soil into groundwater, particularly in well drained, low organic matter soil.

At the proposed application rate and use patterns, run-off and drift of flumetsulam may pose risks to aquatic organisms and terrestrial plants. The observance of spray buffer zones can effectively mitigate the entry of spray drift into aquatic and terrestrial systems. Spray buffer zones will not mitigate runoff. To reduce the potential for runoff of flumetsulam to adjacent aquatic habitats, precautionary statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted are required. In addition, a vegetative strip between the area and the edge of a water body is recommended to reduce runoff of flumetsulam to aquatic areas

### **5.0 Value**

Flumetsulam contributes to weed management in soybean and corn production although the acreage treated is relatively small as compared to those major soybean and corn herbicides. It is mainly used in co-formulation with other herbicides (for example, s-metolachlor or cropyralid) to broaden weed control spectrum. It is principally used in high value non-glyphosate tolerant (Identity Preserved) soybeans grown for the export market. Flumetsulam controls Eastern black nightshade which has “zero tolerance” status in food grade soybean. It provides an alternative mode of action for control of glyphosate resistant common ragweed that are becoming more prevalent in soybean and corn production. It has a wide application window (surface preplant, preplant incorporated, pre-emergence or early post-emergence) which provides growers with more flexibility in managing their farming practices, such as seeding. As a residual herbicide, flumetsulam can be tank-mixed with the non-residual glyphosate to prolong the weed-free duration which assists the crop establishment.

### **6.0 Pest Control Product Policy Considerations**

#### **6.1 Toxic Substances Management Policy Considerations**

The TSMP is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, in other words, persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, flumetsulam and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03 and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Flumetsulam does not meet all Track 1 criteria, and is not considered a Track 1 substance. See Appendix III Table 8 for comparison with Track 1 criteria.
- Flumetsulam does not form any transformation products that meet all Track 1 criteria.

The use of flumetsulam is not expected to result in the entry of TSMP Track-1 substances into the environment.

## 6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the “List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern maintained” in the *Canada Gazette*.<sup>3</sup> The list is used as described in the PMRA Notice of Intent NOI2005-01<sup>4</sup> and is based on existing policies and regulations including DIR99-03 and DIR2006-02<sup>5</sup>, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the flumetsulam products.
- Flumetsulam end-use products do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

## 7.0 Incident Reports

There are no incident reports submitted to the PMRA for products containing flumetsulam (as of 19 November 2012).

<sup>3</sup> *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643; “List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern” and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. “Part 1 Formulants of Health or Environmental Concern,” “Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.”

<sup>4</sup> NOI2005-01, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.

<sup>5</sup> DIR2006-02, *PMRA Formulants Policy and Implementation Guidance Document*.

## **8.0 Organization for Economic Co-operation and Development Status of Flumetsulam**

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 34 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies.

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries. In particular, decisions by an OECD member to prohibit all uses of an active ingredient for health or environmental reasons are considered for relevance to the Canadian situation.

Flumetsulam is currently registered for use in other OECD countries, including the United States of America.

The European Commission withdrew the authorization of plant protection products containing flumetsulam in 2007. However, the European Commission decision was due to withdrawn or incomplete support for the chemical in the European review program and was not as a result of a health or environmental concern (EC, 2007).

No decision by an OECD member country to prohibit all uses of flumetsulam for health or environmental reasons has been identified.

## **9.0 Proposed Re-evaluation Decision**

The PMRA is proposing that products containing flumetsulam for sale and use in Canada are acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment:

- Additional precaution statements to protect workers from handling and bystanders from spray drift, an REI of 12 hours to protect postapplication workers, and a PHI of 90 days for soybeans are proposed.
- Environment precautionary label statements and spray buffer zones to reduce the effects of flumetsulam in the environment are proposed.

The proposed mitigation measures are presented in Appendix V. No additional data are being requested at this time.

## **10.0 Supporting Documentation**

PMRA documents, such as Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, and DACO tables can be found on the Pesticides and Pest Management portion of Health Canada's website at [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra). PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: [pmra.infoserv@hc-sc.gc.ca](mailto:pmra.infoserv@hc-sc.gc.ca)

The federal TSMP is available through Environment Canada's website at [www.ec.gc.ca/toxiques-toxics/default.asp](http://www.ec.gc.ca/toxiques-toxics/default.asp).

## List of Abbreviations

|               |  |
|---------------|--|
| $\mu\text{g}$ | microgram  |
| $1/n$         | exponent for the Freundlich isotherm   |
| ADI           | Acceptable Daily Intake  |
| a.i.          | active ingredient  |
| ARfD          | Acute Reference Dose   |
| atm           | atmosphere(s)  |
| BAF           | Bioaccumulation Factor   |
| BCF           | Bioconcentration Factor  |
| bw            | body weight  |
| CAS           | Chemical Abstracts Service   |
| cm            | centimetre(s)  |
| cPAD          | Chronic Population Adjusted Dose   |
| DACO          | Data Code  |
| DEA           | Dietary Exposure Assessment  |
| $DT_{50}$     | dissipation time 50% (the time required to observe a 50% decline in concentration) |
| $DT_{90}$     | dissipation time 90% (the time required to observe a 90% decline in concentration) |
| dw            | dry weight   |
| $EC_{25}$     | effective concentration on 25% of the population                                   |
| EDE           | Estimated Daily Exposure   |
| EDWC          | Estimated Drinking Water Concentration   |
| EEC           | Expected Environmental Concentration   |
| FC            | Food Consumption   |
| FIR           | Food Ingestion Rate  |
| FIRST         | FQPA Index Reservoir Screening Tool  |
| FQPA          | <i>Food Quality Protection Act</i>   |
| g             | gram(s)  |
| GUS           | Groundwater Ubiquity Score   |
| ha            | hectare  |
| IUPAC         | International Union of Pure and Applied Chemistry                                  |
| $K_d$         | soil-water partition coefficient   |
| kg            | kilogram(s)  |
| $K_F$         | Freundlich adsorption coefficient  |
| $K_{oc}$      | organic-carbon partition coefficient   |
| $K_{ow}$      | <i>n</i> -octanol–water partition coefficient                                      |
| $LC_{50}$     | lethal concentration to 50%  |
| $LD_{50}$     | lethal dose to 50%   |
| LOAEL         | Lowest Observed Adverse Effect Level   |
| LOC           | Level of Concern   |
| LOEC          | Lowest Observed Effect Concentration   |
| LOD           | Limit of Detection   |
| LOQ           | Limit of Quantitation  |
| $\text{m}^3$  | metre(s) cubed   |
| mg            | milligram(s)   |

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|          |   |
|----------|---|
| mm Hg    | millimetre mercury                            |
| MOE      | Margin of Exposure                            |
| MRL      | Maximum Residue Limit                         |
| nm       | nanometre                                     |
| NOEC     | No Observed Effect Concentration              |
| NOEL     | No Observed Effect Level                      |
| pH       | -log <sub>10</sub> hydrogen ion concentration |
| PHED     | Pesticide Handlers Exposure Database          |
| PHI      | Post-Harvest Interval                         |
| PMRA     | Pest Management Regulatory Agency             |
| ppm      | parts per million                             |
| PRVD     | Proposed Re-evaluation Decision               |
| REI      | Restricted-Entry Interval                     |
| RQ       | Risk Quotient                                 |
| SCI-GROW | Screening Concentration in Ground Water       |
| TC       | transfer coefficient                          |
| TGAI     | Technical Grade Active Ingredient             |
| TSMP     | Toxic Substances Management Policy            |
| USEPA    | United States Environmental Protection Agency |
| UV       | ultraviolet                                   |

## Appendix I    Registered Flumetsulam Products as of 19 November 2013

| <b>Registration No.</b> | <b>Product Name</b>                       | <b>Registrant</b>            | <b>Guarantee</b>   | <b>Class</b> | <b>Formulation</b> |
|-------------------------|---|------------------------------|--|--------------|--------------------|
| 24449                   | Flumetsulam Technical Herbicide           | Dow Agrosciences Canada Inc. | Flumetsulam: 98%   | T            | Solid              |
| 25783                   | Striker Manufacturing Concentrate         | Dow Agrosciences Canada Inc. | Flumetsulam: 9.3%<br>2,4-D (present as acid): 50%<br>Clopyralid: 25% | MC           | Wettable Granules  |
| 24450                   | Flumetsulam 75% WDG Herbicide             | Dow Agrosciences Canada Inc. | Flumetsulam: 75%   | C            | Wettable Granules  |
| 26628                   | Broadstrike Dual Magnum Soybean Herbicide | Dow Agrosciences Canada Inc. | Flumetsulam: 45.3 g/L<br>S-Metolachlor and R-enantiomer 879.4 g/L    | C            | Solution           |
| 27004                   | Broadstrike RC Herbicide                  | Dow Agrosciences Canada Inc. | Flumetsulam: 80%   | C            | Wettable Granules  |
| 27005                   | Flumetsulam 80% WDG WSP Herbicide         | Dow Agrosciences Canada Inc. | Flumetsulam: 80%   | C            | Wettable Granules  |
| 27145                   | Fieldstar WDG Herbicide                   | Dow Agrosciences Canada Inc. | Flumetsulam: 18.5%<br>Clopyralid: 50%                                | C            | Soluble Granules   |
| 27146                   | Fieldstar WDG WSP Herbicide               | Dow Agrosciences Canada Inc. | Flumetsulam: 18.5%<br>Clopyralid: 50%                                | C            | Soluble Granules   |

<sup>1</sup> T: Technical; MC: Manufacturing Concentrate; C: Commercial.



## Appendix II    Toxicological Endpoints for Flumetsulam Health Risk Assessments

| Exposure Scenario                      | Dose <sup>1</sup> (mg/kg bw/day) | Study  | CAF or Target MOE <sup>2</sup> |
|--|----------------------------------|--|--------------------------------|
| Acute Dietary                          | No endpoint established.         |  |                                |
| Chronic Dietary                        | NOEL = 100                       | Based on renal toxicity in the 1-year feeding study in the dog   | 100                            |
|  | ADI = 1.0 mg/kg bw/day           |  |                                |
| Short and intermediate-term dermal     | NOEL ≥ 1000                      | Based on lack of treatment-related effects at highest dose tested in a 21-day dermal toxicity study in rabbits | 100                            |
| Short and intermediate-term inhalation | No endpoint established.         |  |                                |
| Cancer                                 | Flumetsulam is not oncogenic.    |  |                                |

<sup>1</sup> NOEL = No Observed Effect Level; ADI = Acceptable Daily Intake

<sup>2</sup> CAF = Composite Assessment Factor; Target MOE = target Margin of Exposure



### Appendix III Environmental Exposure and Risk Assessment for Flumetsulam

**Table 1 Summary of Fate Processes for Flumetsulam in the Terrestrial Environment**

| Process                         | T <sub>1/2</sub> or DT <sub>50</sub> | DT <sub>90</sub> | Kinetics | Comments                            | PMRA Reference    |
|---------------------------------|--------------------------------------|------------------|----------|-------------------------------------|-------------------|
| <b>Abiotic transformation</b>   |                                      |                  |          |                                     |                   |
| Hydrolysis: pH 5, 7 and 9, 25°C | Stable                               | nr               | na       | Not a major route of transformation | 1143797           |
| Phototransformation soil 25°C   | 87 – 90 d                            | nr               | SFO      | Not a major route of transformation | 1143800 / 1143801 |
| <b>Biotic transformation</b>    |                                      |                  |          |                                     |                   |
| Silt loam (Catlin)              | 117                                  | 2495             | IORE     | Moderately persistent               | 1143806           |
| Sandy (Appling)                 | 17.6                                 | 217              | IORE     | Slightly persistent                 |                   |
| Clay (Hoytville)                | 46.6                                 | 500              | DFOP     | Moderately persistent               |                   |
| Loam (Webster)                  | 94.8                                 | 928              | DFOP     | Moderately persistent               |                   |
| Clay (Hoytville)                | 28.7                                 | 265              | DFOP     | Slightly persistent                 |                   |
| Clay (Hoytville)                | 37.7                                 | 191              | DFOP     | Slightly persistent                 |                   |
| Sandy loam (Tama)               | 35.3                                 | 173              | DFOP     | Slightly persistent                 |                   |
| Sandy loam (Hanford)            | 45.8                                 | 152              | SFO      | Moderately persistent               |                   |
| Silt loam (Crofton)             | 13.3                                 | 168              | IORE     | Non-persistent                      |                   |
| Loam (Barnes)                   | 32.5                                 | 330              | IORE     | Slightly persistent                 |                   |
| Sandy clay loam (Milford)       | 70.7                                 | 1374             | DFOP     | Moderately persistent               | 1143808           |
| Silt loam (Hosmer)              | 30.9                                 | 284              | IORE     | Slightly persistent                 |                   |
| Silt loam (Putnam)              | 15.4                                 | 51               | SFO      | Slightly persistent                 |                   |
| Silt loam (Russel)              | 51.4                                 | 263              | DFOP     | Moderately persistent               |                   |
| Silty clay loam (Sharpsburg)    | 36.1                                 | 207              | DFOP     | Slightly persistent                 |                   |
| Silt loam (Crofton)             | 24                                   | 79.8             | SFO      | Slightly persistent                 |                   |
| Silty clay loam (Sharpsburg)    | 32.1                                 | 145              | DFOP     | Slightly persistent                 |                   |
| Silty clay loam (Crofton)       | 150                                  | 630              | DFOP     | Moderately persistent               |                   |
| Silt loam (Ida)                 | 12.4                                 | 41.2             |          | Non-persistent                      |                   |
| Sandy loam (Londo)              | 17.3                                 | 57.5             | SFO      | Slightly persistent                 |                   |
| Silt loam (Commerce)            | 22.4                                 | 74.3             | SFO      | Slightly persistent                 | 1143811           |
| Clay (Mhoon)                    | 45.8                                 | 152              | SFO      | Moderately persistent               |                   |
| Clay loam (Cannisteeo)          | 30.2                                 | 737              | IORE     | Slightly persistent                 |                   |

| Process                       | T <sub>1/2</sub> or DT <sub>50</sub>   | DT <sub>90</sub> | Kinetics | Comments  | PMRA Reference |  |
|-------------------------------|--|------------------|----------|---|----------------|--|
| Clay (Hovtville)              | 33   | 1253             | IORE     | Slightly persistent   |                |  |
| Clay (Perry)                  | 51.5   | 1875             | DFOP     | Moderately persistent   |                |  |
| Clay (Cannistee)              | 38.9   | 129              | SFO      | Slightly persistent   |                |  |
| <b>Mobility</b>               |  |                  |          |   |                |  |
| Adsorption                    | Catlin silt loam   | Kd = 0.34        | Koc = 15 | Very highly mobile  | 1143803        |  |
|                               | Appling sandy loam   | Kd = 0.05        | Koc = 8  | Very highly mobile  |                |  |
|                               | Hovtville clay   | Kd = 0.18        | Koc = 9  | Very highly mobile  |                |  |
|                               | Webster loam   | Kd = 0.19        | Koc = 4  | Very highly mobile  |                |  |
| Leaching                      | Soil column leaching: (Silt loam, pH 6.6, 2.52% OC, soil aged 30 days.)<br><br>39.8% of AR was found in the leachate, while 63.2% remained on the column. The first fraction (0-6 cm) contained greater than 44.6% of the applied radiocarbon (0.021 ppm). The lower fractions each contained <4% of the applied radiocarbon (0.001 ppm). Flumetsulam was the major component found by HPLC analysis of the extracts of the first column segment and leachate. Flumetsulam has a potential for leaching. |                  |          |   |                |  |
| <b>Field Studies</b>          |  |                  |          |   |                |  |
| Terrestrial Field Dissipation | St Thomas, ON, Canada:<br>16 months  | 40 d<br>(SFO)    | NR       | At both sites, residues of flumetsulam were restricted to the upper 15 cm of the soil profile at all sampling times. Flumetsulam transformed to levels corresponding to 24 and 23% of applied mass by the end of the first season (119 and 154 days after application), and to levels corresponding to 3 and 11% of applied mass by the end of the second season (457 and 509 days after application) at the St.Thomas and the Branchton sites, respectively.                           | 1135655        |  |
|                               | Branchton, ON, Canada<br>16 months   | 45 d<br>(SFO)    | NR       |   |                |  |
|                               | Geneseo, IL, U.S.  | 3<br>months      | NR       | At the time of the next season's planting, 4, 9, 15, and 12% of the initial flumetsulam application was still extractable at Midland, Geneseo, Wayside and Burdette.<br><br>Flumetsulam did not leach at the Geneseo or Wayside site. Trace leaching to 45 cm occurred at Midland while flumetsulam moved more apparently through the soil profile at Burdette in the 30-45 cm layer after two weeks, and an isolated detection (<2.5 µg/kg) in the 90-120 cm layer after three months. | 1143813        |  |
|                               | Wayside, MS, U.S.  | 3<br>months      | NR       |   |                |  |
|                               | Midland MI, U.S.   | 1.5<br>months    | NR       |   |                |  |
|                               | Burdette, MS, U.S.   | 1.5<br>months    | NR       |   |                |  |

<sup>1</sup> NR = Not Reported

**Table 2 Summary of Fate Processes for Flumetsulam in the Aquatic Environment**

| <b>Process</b>                     | <b>T<sub>1/2</sub> or DT<sub>50</sub></b> | <b>DT<sub>90</sub></b> | <b>Kinetics</b> | <b>Comments</b>   | <b>PMRA Reference</b> |
|------------------------------------|---|------------------------|-----------------|---|-----------------------|
| <b>Abiotic transformation</b>      |   |                        |                 |   |                       |
| Hydrolysis: pH 5, 7 and 9,<br>25°C | Stable                                    | NR                     | NA              | Not a major route of transformation   | 1143797               |
| Aquatic Phototransformation        | pH 5: 151 d<br>pH 7: 727 d                | NR                     | SFO             | <sup>14</sup> C-aniline label; DT <sub>50</sub> s are approximate values for spring sunshine at ~40°N latitude and 25°C; not a major route of transformation. | 1143798               |
|                                    | pH 5: 164 d<br>pH 7: 330 d                |                        |                 | <sup>14</sup> C-pyrimidine label; not a major route of transformation   | 1143799               |
| <b>Aerobic biotransformation</b>   |   |                        |                 |   |                       |
| Pond water/sediment system         | Whole system:<br>754 – 8824 d             | NR                     | SFO             | Persistent  | 1146708 / 1159712     |
| <b>Anaerobic biotransformation</b> |   |                        |                 |   |                       |
| Water/sediment system              | Whole system:<br>183 d                    | NR                     | SFO             | Persistent  | 1143812               |

<sup>1</sup> NR = Not Reported; NA = Not Applicable

**Table 3 Toxicity of Flumetsulam to Non-Target Species**

| Organism                     | Study type                | Species  | Test material      | Endpoint  | Value   | Effect of concern                 | PMRA Reference |
|------------------------------|---------------------------|--|--------------------|---|---|-----------------------------------|----------------|
| <b>Terrestrial Organisms</b> |                           |  |                    |   |   |                                   |                |
| Earthworm                    | Acute                     | <i>Eisenia foetida</i>   | Technical (97.1%)  | 14-d LC <sub>50</sub><br>14-day NOEC  | >950 mg a.i./kg soil<br>= 950 mg a.i./kg soil   | Mortality                         | 1143843        |
| Bee                          | Contact                   | <i>Apis mellifera</i>  | Technical (99.3%)  | 48-h LD <sub>50</sub>   | > 100 µg a.i./bee   | Mortality                         | 1143842        |
| Birds                        | Acute                     | Bobwhite quail ( <i>Colinus virginianus</i> )  | Technical (99.8%)  | 14-d LD <sub>50</sub>   | >2250 mg a.i./kg bw   | Mortality                         | 1143819        |
|                              | Reproduction              | northern bobwhite quail ( <i>Colinus virginianus</i> )   | Technical (99.61%) | NOEC  | 18-w NOEC = 600 mg a.i./kg diet<br>(70.9 mg a.i./kg bw/day)<br><br>No effect on reproductive parameters at highest test concentration.      |                                   | 1143841        |
|                              |                           | mallard duck ( <i>Anas platyrhynchos</i> )   |                    | NOEC  | 20-w NOEC = 300 mg a.i./kg diet<br>(32.5 mg a.i./kg bw/day)<br><br>Based on slight reduction in viable embryos as a percentage of eggs set. |                                   | 1143823        |
| Mammals                      | Acute                     | Rat  | Technical (99.61%) | LD <sub>50</sub>  | > 5000 mg a.i./kg bw  | Survival                          | 1143748        |
|                              | 2 generation reproduction | Rat  | Technical          | NOEL  | NOEL = 1000 mg a.i./kg day for systemic toxicity and for reproductive and developmental toxicity, the highest dose tested.                  |                                   | 2252169        |
| Vascular plants              | Seedling emergence        | 4 monocot species: corn, onion, ryegrass, oat<br>8 dicot species: cabbage, cucumber, lettuce, radish, rape, soybean, sugar beet, tomato. | Technical          | Most sensitive species was rapeseed.<br>NOEC = 8.5 g a.i./ha; EC <sub>25</sub> = 8.9 g a.i./ha (based on reduced shoot length).   |   |                                   | 1159715        |
|                              | Vegetative vigour         |  |                    | Most sensitive species was rapeseed.<br>NOEC = 0.10 g a.i./ha; EC <sub>25</sub> = 0.11 g a.i./ha (based on reduced shoot length). |   |                                   |                |
| <b>Freshwater Organisms</b>  |                           |  |                    |   |   |                                   |                |
| Invertebrates                | Acute                     | <i>Daphnia magna</i>   | Technical (99.7%)  | 48-h LC <sub>50</sub><br>NOEC   | 590 mg a.i./L<br>174 mg a.i./L  | immobility                        | 1143854        |
|                              | Chronic                   | <i>Daphnia magna</i>   | Technical (99%)    | 21-d NOEC   | >200 mg a.i./L  | survival and reproductive effects | 1911873        |

| Organism                              | Study type | Species   | Test material     | Endpoint                                   | Value                                | Effect of concern  | PMRA Reference |
|---------------------------------------|------------|---|-------------------|--|--------------------------------------|--|----------------|
| Fish                                  | Acute      | Rainbow trout<br>( <i>Oncorhynchus mykiss</i> )   | Technical (99.7%) | 96-h LC <sub>50</sub><br>NOEC              | >300 mg a.i./L<br>300 mg a.i./L      | mortality  | 1143867        |
|                                       |            | Fathead minnow ( <i>Pimephales promelas</i> )   | Technical (99.7%) | 96-h LC <sub>50</sub><br>NOEC              | >293 mg a.i./L<br>293 mg a.i./L      |  | 1143872        |
|                                       | Chronic    | Bluegill sunfish ( <i>Lepomis macrochirus</i> )   | Technical (99.7%) | 96-h LC <sub>50</sub><br>NOEC              | >319 mg a.i./L<br>319 mg a.i./L      | Percent hatched,<br>percent normal<br>larvae at hatch,<br>survival, growth | 1143871        |
|                                       |            | Fathead minnow ( <i>Pimephales promelas</i> )   | Technical (99.6%) | 32 day early<br>life stage<br>NOEC<br>LOEC | 197 mg a.i./L<br>>197 mg a.i./L      |  | 1146724        |
| Algae                                 | Acute      | Green algae<br>( <i>Pseudokirchneriella subcapitata</i> - formerly known as <i>Seleniastrum capricornutum</i> ) | Technical (99.6%) | 5-d EC <sub>50</sub><br>NOEC               | 4.93 mg a.i./L<br>0.36 mg a.i./L     | Cell density<br><br>Cell density,<br>biomass and growth<br>rate            | 1143877        |
|                                       |            | Freshwater diatom ( <i>Navicula pelliculosa</i> )   | Technical (99.6%) | 5-d EC <sub>50</sub><br>NOEC               | 51.1 mg a.i./L<br>44.2 mg a.i./L     |  | 19116726       |
|                                       |            | Freshwater blue-green algae<br>( <i>Anabaena flos-aquae</i> )   | Technical (99.6%) | 5-d EC <sub>50</sub><br>NOEC               | 0.167 mg a.i./L<br><0.122 mg a.i./L  | Cell count   | 1146726        |
| Vascular Plants                       | Acute      | Duckweed<br>( <i>L. gibba</i> )   | Technical (99.6%) | 14-d EC <sub>50</sub><br>14-d NOEC         | 0.0051 mg a.i./L<br>0.0039 mg a.i./L | Frond count  | 1146725        |
| <b>Marine and estuarine Organisms</b> |            |   |                   |  |                                      |  |                |
| >349 mg a.i./L<br>≥349 mg a.i./L      | Mortality  | Grass shrimp<br>( <i>Palaeomonetes vulgaris</i> )   | Technical (99.6%) | 96-h EC <sub>50</sub><br>NOEC              | >349 mg a.i./L<br>≥349 mg a.i./L     | Mortality  | 1143875        |
| >173 mg a.i./L                        |            | Eastern oysters ( <i>Crassostrea virginica</i> )  | Technical (99.8%) | 96-h EC <sub>50</sub><br>NOEC              | >173 mg a.i./L<br>≥173 mg a.i./L     | Shell deposition   | 1143874        |
| >379 mg a.i./L                        | Mortality  | Atlantic silverside ( <i>Menidia menidia</i> )  | Technical (99.8%) | 96-h EC <sub>50</sub><br>NOEC              | >379 mg a.i./L<br>≥379 mg a.i./L     | Mortality  | 1143873        |
| 50 mg a.i./L<br>61.3 mg a.i./L        | Cell count | Marine diatom ( <i>Skeletonema costatum</i> )   | Technical (99.6%) | 120-h EC <sub>50</sub><br>NOEC             | 50 mg a.i./L<br>61.3 mg a.i./L       | Growth inhibition  | 1146677        |

<sup>†</sup> NA = Not Applicable; CND = Could Not Determine; NOEC = No Observed Effect Concentration, NOEL = No Observed Effect Level; LD = Lethal Dose; LC = Lethal Concentration

**Table 4 Screening Level Risk Assessment for Earthworms and Bees**

| <b>Organisms</b> | <b>Exposure</b> | <b>Endpoint Value</b>                                     | <b>Application Rate</b> | <b>EEC<sup>1</sup></b> | <b>RQ<sup>2</sup></b> |
|------------------|-----------------|---|-------------------------|------------------------|-----------------------|
| Earthworm        | Acute           | 14-day LC <sub>50</sub> ÷ 2:<br>>425 mg a.i./kg soil      | 70 g a.i./ha            | 0.031mg a.i./kg        | <0.0001               |
| Bee              | Acute contact   | 48-h LD <sub>50</sub> :<br>> 100 µg a.i./bee <sup>3</sup> | 70 g a.i./ha            | 70 g a.i./ha           | <0.01                 |

Atkins EL., Kellum D., Atkins KW. 1981. Reducing pesticide hazards to honey bees: mortality prediction techniques and integrated management techniques. Univ Calif, Div Agric Sci, Leaflet 2883, 22 pp (PMRA 1573066)

<sup>1</sup> The Expected Environmental Concentration (EEC) in soil was calculated based on the maximum single application made to bare soil with a soil density of 1.5 g/cm<sup>3</sup> and even mixing through a 15 cm depth. Bee: maximum single application rate.

<sup>2</sup> Risk Quotient (RQ) = exposure/toxicity. Risk quotients shown in bold exceed the level of concern (RQ > 1).

<sup>3</sup> Toxicity in µg bee converted to the equivalent kg a.i./ha using a conversion factor of 1.12 (Atkins et al., 1981).

**Table 5 Screening Level Risk Assessment for Birds**

| <b>Study type</b>                 | <b>Toxicity<br/>(mg a.i./kg bw/d)</b> | <b>Feeding Guild (food item)</b> | <b>EDE<sup>1</sup><br/>(mg a.i./kg bw)</b> | <b>RQ<sup>2</sup></b> | <b>LOC<sup>1</sup><br/>Exceeded?</b> |
|-----------------------------------|---------------------------------------|----------------------------------|--|-----------------------|--------------------------------------|
| <b>Small Bird (0.02 kg)</b>       |                                       |                                  |  |                       |                                      |
| Acute                             | 225                                   | Insectivore (small insects)      | 3.53                                       | 0.02                  | No                                   |
| Reproduction                      | 32.5                                  | Insectivore (small insects)      | 3.53                                       | 0.11                  | No                                   |
| <b>Medium Sized Bird (0.1 kg)</b> |                                       |                                  |  |                       |                                      |
| Acute                             | 225                                   | Insectivore (small insects)      | 2.75                                       | 0.01                  | No                                   |
| Reproduction                      | 32.5                                  | Insectivore (small insects)      | 2.75                                       | 0.08                  | No                                   |
| <b>Large Sized Bird (1 kg)</b>    |                                       |                                  |  |                       |                                      |
| Acute                             | 225                                   | Herbivore (short grass)          | 2.87                                       | 0.01                  | No                                   |
| Reproduction                      | 32.5                                  | Herbivore (short grass)          | 2.87                                       | 0.09                  | No                                   |

EDE = Estimated Daily Exposure; RQ = Risk Quotient; LOC = Level of Concern

**Table 6 Screening Level Risk Assessment for Mammals**

|                                       | Toxicity<br>(mg a.i./kg bw/d) | Feeding guild (food item)   | EDE <sup>1</sup><br>(mg a.i./kg bw) | RQ <sup>1</sup> | LOC <sup>1</sup><br>exceeded? |
|---------------------------------------|-------------------------------|-----------------------------|-------------------------------------|-----------------|-------------------------------|
| <b>Small mammals (0.015 kg)</b>       |                               |                             |                                     |                 |                               |
| Acute                                 | 500                           | Insectivore (small insects) | 2.03                                | <0.01           | No                            |
| Reproduction                          | 1000                          | Insectivore (small insects) | 2.03                                | 0.002           | No                            |
| <b>Medium Sized mammals (0.035kg)</b> |                               |                             |                                     |                 |                               |
| Acute                                 | 500                           | Herbivore (short grass)     | 6.36                                | 0.01            | No                            |
| Reproduction                          | 1000                          | Herbivore (short grass)     | 11.98                               | 0.006           | No                            |
| <b>Large Sized mammal (1 kg)</b>      |                               |                             |                                     |                 |                               |
| Acute                                 | 500                           | Herbivore (short grass)     | 3.40                                | 0.01            | No                            |
| Reproduction                          | 1000                          | Herbivore (short grass)     | 6.40                                | 0.003           | No                            |

EDE = Estimated Daily Exposure; RQ = Risk Quotient; LOC = Level of Concern

**Table 7 Summary of the Risk of Flumetsulam to Aquatic Organisms: Screening Level**

| Organism                    | Exposure | Species   | Endpoint reported<br>(mg a.i./L) | Endpoint for RA <sup>1</sup><br>(mg a.i./L) | EEC <sup>2</sup><br>(mg a.i./L) | RQ <sup>3</sup> | LOC <sup>3</sup><br>exceeded |
|-----------------------------|----------|---|----------------------------------|---|---------------------------------|-----------------|------------------------------|
| <b>Freshwater organisms</b> |          |   |                                  |   |                                 |                 |                              |
| Invertebrate                | Acute    | Daphnid<br>( <i>Daphnia magna</i> )                                 | LC <sub>50</sub> = 590           | 295   | 0.0088                          | <0.0001         | No                           |
|                             | Chronic  | Daphnid<br>( <i>Daphnia magna</i> )                                 | NOEC = 200                       | 200   | 0.0088                          | <0.0001         | No                           |
| Fish                        | Acute    | Fathead minnow<br>( <i>Pimephales promelas</i> )                    | LC <sub>50</sub> >293            | 29.3  | 0.0088                          | <0.001          | No                           |
|                             | Chronic  |   | NOEC = 197                       | 197   | 0.0088                          | <0.0001         | No                           |
| Amphibian                   | Acute    | Surrogate fish:<br>Fathead minnow<br>( <i>Pimephales promelas</i> ) | LC <sub>50</sub> > 293           | 29.3  | 0.0467                          | <0.01           | No                           |
|                             | Chronic  | Surrogate fish:<br>Fathead minnow<br>( <i>Pimephales promelas</i> ) | NOEC = 197                       | 197   | 0.0467                          | <0.001          | No                           |
| Algae                       | Acute    | Green algae<br>( <i>Seleniastrum capricornutum</i> )                | EC50 = 0.0049                    | 0.0025                                      | 0.0088                          | 3.5             | No                           |
| Aquatic vascular plant      | Acute    | Duckweed<br>( <i>Lemna gibba G3</i> )                               | EC50 = 0.0051                    | 0.0025                                      | 0.0088                          | 3.5             | No                           |

| Organism                          | Exposure | Species  | Endpoint reported (mg a.i./L) | Endpoint for RA <sup>1</sup> (mg a.i./L) | EEC <sup>2</sup> (mg a.i./L) | RQ <sup>3</sup> | LOC <sup>3</sup> exceeded |
|-----------------------------------|----------|--|-------------------------------|--|------------------------------|-----------------|---------------------------|
| <b>Marine/Estuarine organisms</b> |          |  |                               |  |                              |                 |                           |
| Invertebrate                      | Acute    | Eastern oysters ( <i>Crassostrea virginica</i> ) | LC <sub>50</sub> >173         | 86.5                                     | 0.0088                       | <0.001          | No                        |
| Fish                              | Acute    | Atlantic silverside ( <i>Menidia menidia</i> )   | LC <sub>50</sub> >379         | 37.9                                     | 0.0088                       | <0.001          | No                        |
| Marine algae                      | Acute    | <i>Skeletonema costatum</i>                      | 120-h EC <sub>50</sub>        | 61.3                                     | 0.0088                       | <0.001          | No                        |

<sup>1</sup> Endpoints used in the acute exposure Risk Assessment (RA) are derived by dividing the EC<sub>50</sub> or LC<sub>50</sub> from the appropriate laboratory study by a factor of two for aquatic invertebrates and plants, and by a factor of ten for fish and amphibians.

<sup>2</sup> Expected Environmental Concentration (EEC) based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms (see section 2.9.2).

<sup>3</sup> RQ = Risk Quotient; LOC = Level of Concern; NOEC = No Observed Effect Concentration; LC = Lethal Concentration

**Table 8 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria**

| TSMP Track 1 Criteria  | TSMP Track 1 Criterion value                 |  |  | Flumetsulam:<br>Are criteria met?   |
|--|--|--|--|---|
| Toxic or toxic equivalent as defined by the Canadian Environmental Protection Act <sup>1</sup> | Yes  |  |  | Yes   |
| Predominantly anthropogenic <sup>2</sup>   | Yes  |  |  | Yes   |
| Persistence <sup>3</sup> :   | Soil   | Half-life<br>≥ 182 days                                |  | No: 12.4–150 days   |
|  | Water  | Half-life<br>≥ 182 days                                |  | Yes: >182 days  |
|  | Sediment                                     | Half-life<br>≥ 365 days                                |  | Not available   |
|  | Air  | Half-life ≥ 2 days or evidence of long range transport |  | Half-life or volatilization is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (133 x 10 <sup>-15</sup> Pa at 25°C) and Henry's Law Constant (7.57 x 10 <sup>-9</sup> atm m <sup>3</sup> /mole). |
| Bioaccumulation <sup>4</sup>   | Log K <sub>OW</sub> ≥ 5                      |  |  | No: 0.21  |
|  | BCF ≥ 5000                                   |  |  | Not available   |
|  | BAF ≥ 5000                                   |  |  | Not available   |
| Is the chemical a TSMP Track 1 substance (all four criteria must be met)?                      | No, does not meet all TSMP Track 1 criteria. |  |  |   |

<sup>1</sup>All pesticides will be considered toxic or toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the toxicity criterion may be refined if required (in other words, all other TSMP criteria are met).

<sup>2</sup>The policy considers a substance "predominantly anthropogenic" if, based on expert judgment, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

<sup>3</sup>If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

<sup>4</sup>The log K<sub>OW</sub> and/or Bioconcentration Factor (BCF) and/or Bioaccumulation Factor (BAF) are preferred over n-Octanol/water partition coefficient (log K<sub>OW</sub>).

## Appendix IV Water Monitoring Data for Flumetsulam

Monitoring data were available from corn and soybean growing areas of Ontario and Quebec as well as Prince Edward Island and the Midwestern United States of America. Groundwater monitoring data were only available from the United States. A summary of the data is provided below, and in Table 8.

Although the number of monitoring studies available for flumetsulam was fairly small, the data available are considered relevant to the Canadian use pattern. The data are fairly recent (mostly collected between 2002 and 2008) and are from corn and soybean growing regions of Canada and the United States. The sampling generally occurred during summer months, which corresponds to the period of use for flumetsulam.

Based on the available data, flumetsulam seems to be routinely detected in surface water bodies located in soybean and corn growing regions of Eastern Canada and the Midwestern United States. However, the levels detected are generally quite low. The maximum detections across all areas were approximately 1.1 µg/L. However, the majority of samples had flumetsulam concentrations which were orders of magnitude below 1 µg/L. These low concentrations are likely a function of the low application rate for sulfonylurea herbicides.

Although no Canadian data were available for flumetsulam in groundwater, data from America, mainly from the NAWQA database which targets agricultural areas, indicate that flumetsulam is rarely detected in groundwater (<1% detection in approximately 2700 samples). When detected, the levels of flumetsulam were low; the maximum concentration detected in groundwater was 0.075 µg/L.

**Table 1 Summary of the Monitoring Studies Available**

| Data Source  | DETECTION FREQUENCY                                     |  |   |   |                       | CONCENTRATION (µg/L) |       |              |  |
|--|---|--|---|---|-----------------------|----------------------|-------|--------------|--|
|  | Location  | Min detection or detection limit (µg/L.) | # of systems tested (or absolute number of samples) | # of systems or samples with detections | % detection frequency | Mean detection       | 95th  | Absolute max | Arithmetic mean including non-detects at % LOD |
| <b>Fluorosulam residues in municipal drinking water sources and ground water</b> |   |  |   |   |                       |                      |       |              |  |
| PMRA 2267501   | United States – treated water NAWQA (2004-2009)         | 0.01-0.06                                | 159   | 2                                       | 1.3                   | 0.031                | 0.047 | 0.049        | 0.0245   |
|  | United States – groundwater NAWQA (1999-2012)           | 0.011-0.1732                             | 2717  | 23                                      | 0.8                   | 0.029                | 0.068 | 0.075        | 0.0222   |
| PMRA 2267516   | United States – groundwater in Midwestern States (1998) | 0.01                                     | 25  | 3                                       | 12                    | NA                   | NA    | 0.035        | NA   |
| PMRA 1857396   | United States finished drinking water (2002)            | 0.006                                    | 230   | 3                                       | 1.3                   | NA                   | NA    | 0.01         | NA   |
| PMRA 1857388   | United States finished drinking water (2003)            | 0.006-0.2                                | 321   | 9                                       | 2.8                   | NA                   | NA    | 0.01         | NA   |
| PMRA 1852616   | United States finished drinking water (2004)            | 0.006-0.196                              | 233   | 0                                       | 0                     | NA                   | NA    | NA           | NA   |
| PMRA 1852618   | United States finished drinking water (2005)            | 0.006-0.129                              | 230   | 4                                       | 1.7                   | NA                   | NA    | 0.01         | NA   |
| PMRA 1852619   | United States finished drinking water (2006)            | 0.006-0.129                              | 365   | 0                                       | 0                     | NA                   | NA    | NA           | NA   |
| PMRA 1774484   | United States finished drinking water (2007)            | 0.006-0.128                              | 368   | 0                                       | 0                     | NA                   | NA    | NA           | NA   |
| PMRA 1852614   | United States finished drinking water (2008)            | 0.006-0.2                                | 309   | 0                                       | 0                     | NA                   | NA    | NA           | NA   |

| Flumetsulam residues in ambient water that may serve as a drinking water source |  |                         |      |       |    |    |      |       |       |       |       |
|---|--|-------------------------|------|-------|----|----|------|-------|-------|-------|-------|
| PMRA 1398451,<br>1398452, 1398453   | Corn and<br>Soybean<br>region of<br>Quebec | Chibouet<br>River       | 2002 | 0.02  | 42 | 13 | 31.0 | 0.09  | 0.33  | 0.41  | 0.04  |
|   |  |                         | 2003 | 0.08  | 41 | 2  | 4.9  | 0.17  | 0.21  | 0.21  | 0.05  |
|   |  |                         | 2004 | 0.08  | 37 | 25 | 67.6 | 0.05  | 0.11  | 0.14  | 0.05  |
|   |  | des Hurons<br>River     | 2002 | 0.02  | 42 | 16 | 38.1 | 0.07  | 0.15  | 0.26  | 0.03  |
|   |  |                         | 2003 | 0.08  | 41 | 2  | 4.9  | 0.09  | 0.09  | 0.09  | 0.04  |
|   |  | Saint-Régis<br>River    | 2002 | 0.02  | 40 | 5  | 12.5 | 0.04  | 0.05  | 0.05  | 0.01  |
|   |  |                         | 2003 | 0.08  | 39 | 1  | 2.6  | 0.1   | 0.1   | 0.1   | 0.04  |
|   |  | Saint-Zéphirin<br>River | 2003 | 0.08  | 39 | 1  | 2.6  | 0.43  | 0.43  | 0.43  | 0.05  |
| PMRA 2102602  | Corn and<br>Soybean<br>region of<br>Quebec | Chibouet<br>River       | 2005 | 0.007 | 40 | 16 | 40.0 | 0.014 | 0.02  | 0.023 | 0.008 |
|   |  |                         | 2006 | 0.007 | 39 | 13 | 33.3 | 0.01  | 0.017 | 0.021 | 0.006 |
|   |  |                         | 2007 | 0.007 | 43 | 2  | 4.7  | 0.012 | 0.014 | 0.014 | 0.004 |
|   |  | des Hurons<br>River     | 2005 | 0.007 | 38 | 27 | 71.1 | 0.016 | 0.03  | 0.037 | 0.012 |
|   |  |                         | 2006 | 0.007 | 34 | 25 | 73.5 | 0.016 | 0.044 | 0.097 | 0.013 |
|   |  |                         | 2007 | 0.007 | 43 | 19 | 44.2 | 0.024 | 0.085 | 0.095 | 0.012 |
|   |  | Saint-Régis<br>River    | 2005 | 0.007 | 38 | 1  | 2.6  | 0.007 | 0.007 | 0.007 | 0.004 |
|   |  |                         | 2006 | 0.007 | 33 | 3  | 9.1  | 0.031 | 0.054 | 0.057 | 0.006 |
|   |  |                         | 2007 | 0.007 | 43 | 3  | 7.0  | 0.016 | 0.019 | 0.019 | 0.004 |

| Flumetsulam residues in ambient water that may serve as a drinking water source |   |                                  |              |       |    |      |        |        |                     |        |       |
|---|---|----------------------------------|--------------|-------|----|------|--------|--------|---------------------|--------|-------|
|   |   | Saint-Zéphirin River             | 2005         | 0.007 | 3  | 2    | 66.7   | 0.02   | 0.023               | 0.023  | 0.015 |
|   |   |                                  | 2006         | 0.007 | 33 | 12   | 36.4   | 0.024  | 0.08                | 0.12   | 0.011 |
|   |   |                                  | 2007         | 0.007 | 42 | 5    | 11.9   | 0.018  | 0.028               | 0.030  | 0.005 |
| PMRA 1739256  | Ontario sites<br>(June-Sept.<br>2007)                                       | Blyth                            | 0.00131      | 4     | 3  | 75.0 | 0.0085 | 0.020  | 0.0224 <sup>2</sup> | 0.0065 |       |
|   |   | Spenser                          | 0.00131      | 4     | 0  | 0    | NA     | NA     | NA                  | 0.0006 |       |
|   |   | Nissouri                         | 0.00131      | 4     | 2  | 50.0 | 0.0050 | 0.0062 | 0.0068              | 0.0028 |       |
|   | Quebec sites<br>in Yamaska<br>River basin<br>(June-Aug.<br>2007)            | Noire River                      | 0.00131      | 4     | 0  | 0    | NA     | NA     | NA                  | 0.0006 |       |
|   |   | Yamaska River                    | 0.00131      | 4     | 1  | 25.0 | 0.0019 | 0.0019 | 0.0019              | 0.001  |       |
|   |   | Yamaska River at St.<br>Hyacinth | 0.00131      | 4     | 0  | 0    | NA     | NA     | NA                  | 0.0006 |       |
| PMRA 2101142  | Southern Ontario streams,<br>agricultural reservoirs,<br>urban control site | 2006                             | 0.00131      | 150   | 59 | 39.3 | 40     | NA     | 1.1                 | NA     |       |
|   |   | 2007                             | 0.00131      | 120   | 16 | 13.3 | NA     | NA     | 0.0224              | NA     |       |
|   |   | 2008                             | 0.00066      | 129   | 45 | 34.9 | NA     | NA     | 0.233               | NA     |       |
| PMRA 2267501  | United States – surface water<br>NAWQA (1999-2012)                          |                                  | 0.011-0.1892 | 2825  | 64 | 2.3  | 0.085  | 0.344  | 1.083               | 0.0243 |       |
| PMRA 2267500  | United States – surface water in Iowa<br>STORET (June and July 2005)        |                                  | 0.005        | 41    | 12 | 29.3 | 0.011  | 0.024  | 0.025               | 0.0049 |       |
| PMRA 2267516  | United States – Midwestern streams<br>and rivers (1998)                     |                                  | 0.01         | 130   | 82 | 63.1 | NA     | NA     | 0.358               | NA     |       |
|   | United States – Midwestern<br>reservoirs (1998)                             |                                  | 0.01         | 7     | 4  | 57.1 | NA     | NA     | NR                  | NA     |       |

| <b>Flumetsulam residues in water that is unlikely to be used as drinking water sources</b> |   |             |     |   |     |    |    |       |        |
|--|---|-------------|-----|---|-----|----|----|-------|--------|
| PMRA 1763866   | PEI—surface water (Wilmot and Dunn) (2008)                  | 0.00066     | 9   | 0 | 0   | NA | NA | NA    | 0.0003 |
| PMRA 1852616   | USDA – raw water at intake to treatment plants (2004)       | 0.006-0.196 | 233 | 1 | 0.4 | NA | NA | 0.024 | NA     |
| PMRA 1852618   | USDA– untreated water at intake to treatment plants (2005)  | 0.006-0.129 | 231 | 7 | 3.0 | NA | NA | 0.01  | NA     |
| PMRA 1852619   | USDA – untreated water at intake to treatment plants (2006) | 0.006-0.129 | 367 | 0 | 0   | NA | NA | NA    | NA     |
| PMRA 1774484   | USDA – untreated water at intake to treatment plants (2007) | 0.006-0.128 | 362 | 0 | 0   | NA | NA | NA    | NA     |
| PMRA 1852614   | USDA – untreated water at intake to treatment plants (2008) | 0.006-0.02  | 308 | 0 | 0   | NA | NA | NA    | NA     |

<sup>1</sup> NR = Not Reported; NA = Not Applicable, or cannot be calculated based on available data

<sup>2</sup> Likely the same sample as that reported in PMRA 2101142



## Appendix V    Proposed Label Amendments for Products Containing Flumetsulam

The label amendments presented below do not include all label requirements for individual products, such as first-aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the below label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

### Technical Class Product:

- I) The following warning statement should appear on the **Primary** panel of the technical product labels:



- CAUTION POISON

- II) The following statements are to be added to the "**Environmental Hazards**" section of the Flumetsulam Technical products label:

- TOXIC to aquatic organisms and non-target terrestrial plants.

- III) The following statements are required under the "**Precautions**" Section of the Flumetsulam Technical product label:

- Harmful if inhaled. Avoid inhaling/breathing dusts, vapours or spray mist.
- DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

### Commercial Class Product:

- I) The following statements must be included in a section entitled "**Precautions**."

- Do not enter or allow worker entry into treated areas during the Restricted-Entry Interval (REI) of 12 hours.
- Apply only when the potential for spray drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

- II) The following statements are to be added to the “**Directions for Use**” section of products registered for use on soybean:
  - The Pre-Harvest Interval (PHI) for soybean is 90 days.
- III) The following statements are to be added to the “**Environmental Hazards**” section of all product labels:
  - TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.
  - To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.
  - Avoid application of this product when heavy rain is forecast.
  - Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.
  - The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (*e.g.* sandy soil) and/or the depth to the water table is shallow.
- IV) The following statements are required under the “**Directions for Use**” Section on all product labels:
  - As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.
  - DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.
  - Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.
  - DO NOT apply by air.

**For flumetsulam-only products:****Buffer zones:**

- Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.
- The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, wood lots, hedgerows, riparian areas and shrublands), and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

| Method of application | Crop              | Buffer Zones Required for the Protection of: | Buffer Zones (Metres) Required for the Protection of: | Buffer Zones (Metres) Required for the Protection of: |
|-----------------------|-------------------|--|---|---|
|                       |                   | Freshwater Habitat of Depths: Less than 1 m  | Freshwater Habitat of Depths: Greater than 1 m        | Terrestrial habitat                                   |
| Field sprayer         | Hybrid field corn | 1  | 1   | 15  |
| Field sprayer         | Soybean           | 1  | 1   | 20  |

- For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

**For Broadstrike EPs (flumetsulam + S-metolachlor; Reg. Nos. 26628 and 27004):****Buffer zones:**

- Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.
- The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

| Method of application | Crop    | Buffer Zones (metres) Required for the Protection of: | Buffer Zones (metres) Required for the Protection of: | Buffer Zones (metres) Required for the Protection of: |
|-----------------------|---------|---|---|---|
|                       |         | Aquatic Habitat: Less than 1 m                        | Aquatic Habitat: Greater than 1 m                     | Terrestrial habitat                                   |
| Field sprayer         | Soybean | 25  | 25  | 20  |

- For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

**For Fieldstar End-use Products (flumetsulam + clopyralid; Reg. Nos. 27145 and 27146):**

**Buffer zones:**

- Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.
- The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, wood lots, hedgerows, riparian areas and shrublands), and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

| Method of application | Crop              | Buffer Zones (metres) Required for the Protection of: | Buffer Zones (metres) Required for the Protection of: | Buffer Zones (metres) Required for the Protection of: |
|-----------------------|-------------------|---|---|---|
|                       |                   | Freshwater Habitat of Depths: Less than 1 m           | Freshwater Habitat of Depths: Greater than 1 m        | Terrestrial habitat                                   |
| Field sprayer         | Hybrid field corn | 1   | 1   | 15  |

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

## References

### A. Studies considered for the Chemistry Assessment

#### LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

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|----------------------|--|
| 1423196              | 1991, Series 63: Physical and Chemical Characteristics of DE-498, DACO: 2.16 CBI   |
| 1418897              | 1991, Spectoscopic Identification of DE-498 Herbicide, AGR Sample 291668, DACO: 2.16 CBI   |
| 1916180              | 2010, Group A- Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Discussion of Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method for Flumetsulam 98% Milled Concentrate. DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4. CBI |

### B. Studies considered for the Toxicological Risk Assessment

#### LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

| PMRA Document Number | Reference   |
|----------------------|---|
| 1143731              | Xrd-498: A 2-Week Dietary Probe Study In B6C3F1 Mice (Dr-0238-5651-001)(Flumetsulam), DACO: 4.3.1   |
| 1143732              | Xrd-498: A 13-Week Dietary Toxicity Study In B6C3F1 Mice Final Report (Dr-0238-5651-006)(Flumetsulam), DACO: 4.3.1                        |
| 1143733              | Xrd-498: 2-Week Dietary Probe Study In Fischer 344 Rats Final Report (Dr-0238-5651-003)(Flumetsulam), DACO: 4.3.1                         |
| 1143735              | Xrd-498: 4-Week Dietary Toxicity Study In Male Fischer 344 Rats Final Report (Dr-0238-5651-013)(Flumetsulam), DACO: 4.3.1                 |
| 1143736              | Xrd-498: Results Of A 13-Week Dietary Toxicity Study In Fischer 344 Rats Final Report (Dr-0238-5651-007)(Flumetsulam), DACO: 4.3.1        |
| 1143737              | Xrd-498: Two Week Dietary Toxicity Probe Study In Beagle Dogs Final Report (Dr-0238-5651-016;Dr-0238-5651-016P)(Flumetsulam), DACO: 4.3.1 |
| 1143739              | Xrd-498: 13-Week Dietary Toxicity Study In Beagle Dogs Final Report (Dr-0238-5651-018;-018B;-018P)(Flumetsulam), DACO: 4.3.1              |
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- 1143770 Evaluation Of 2,6-Difluoroaniline In The Ames Salmonella/Mammalian Microsome Bacterial Mutagenicity Assay Final Report (Dr-0275-6276-003)(Flumetsulam), DACO: 4.5.4
- 1143771 Xrd-498: Two-Year Dietary Oncogenicity Study In B6C3F1 Mice Final Report (Dr-0238-5651-011)(Flumetsulam)(Cont'D On Roll #1032), DACO: 4.4.2
- 1143773 Xrd-498: Results Of A Two-Generation Reproduction Study In Fischer 344 Rats Final Report (Dr-0238-5651-021;-021F1;-021Fa;021Fb;-021F2)(Flumetsulam), DACO: 4.5.1
- 1143774 Xrd-498: Dietary Teratology Study In Fischer 344 Rats Final Report (Dr-0238-5651-015)(Flumetsulam), DACO: 4.5.2
- 1143775 Xrd-498: Dietary Teratology Study In Fischer 344 Rats Final Report Addendum (Dr-0238-5651-015)(Flumetsulam), DACO: 4.5.2
- 1143776 Xrd-498: Oral Teratology Probe Study In New Zealand White Rabbits Final Report (Dr-0238-5651-017;-017A;-017B)(Flumetsulam), DACO: 4.5.2
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- 1143778 Evaluation Of Xrd-498 In The Ames Salmonella/Mammalian Microsomal Mutagenicity Assay Final Report (Dr-0238-5651-002)(Flumetsulam), DACO: 4.5.4
- 1143780 The Evaluation Of Xrd-498 In The Rat Hepatocyte Unscheduled Dna Synthesis (Uds) Assay Final Report (Dr-0238-5651-005)(Flumetsulam), DACO: 4.5.4
- 1143785 Xrd-498: Two Year Dietary Oncogenicity Study In B6C3F1 Mice Final Report (Dr-0238-5651-011)(Flumetsulam), DACO: 4.4.2
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- 1143807 Xrd-498: Tissue Distribution And Metabolism Of 14C-Labelled Xrd-498 In Fischer 344 Rats (Dr-0238-5651-(27R)(Flumetsulam), DACO: 6.4

## C. Studies considered for the Occupational Risk Assessment

### LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

#### Unpublished Information

| PMRA Document Number | Reference   |
|----------------------|---|
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## D. Studies considered for the Dietary Risk Assessment

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## E. Studies considered in the Environmental Risk Assessment

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| PMRA Document Number | Reference  |
|----------------------|--|
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| 1143798              | Sunlight Photodegradation Of [14c-Aniline] Xrd-498 In A Buffered Aqueous Solution At Ph5 And 7 (Gh-C 2534;89103;211w-1;211w)(Flumetsulam), DACO: 8.2.1 |
| 1143799              | Sunlight Photodegradation Of [14c-Pyrimidine] Xrd-498 In A Buffered Aqueous Solution At Ph5 And 7 (89102;210w-1;210w)(Flumetsulam), DACO: 8.2.1        |
| 1143800              | Photodegradation Of [14c-Pyrimidine] Xrd-498 On Soil By Natural Sunlight (Gh-C 2452;208w;89088)(Flumetsulam), DACO: 8.2.1                              |
| 1143801              | Photodegradation Of [14c-Aniline] Xrd-498 On Soil By Natural Sunlight (Gh-C 2521;209w-1;209w;89089)(Flumetsulam), DACO: 8.2.1                          |
| 1143803              | Soil Adsorption/Desorption Of 14c-Xrd-498 (Gh-C 2159) (Flumetsulam), DACO: 8.2.4.1   |

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- 1143808 Aerobic Soil Metabolism Of Aniline-Labeled De-498 In Hoytville Soil (Gh-C 2536;89002)(Flumetsulam), DACO: 8.2.3.1
- 1143809 Metabolism Of De-498 In Hoytville Soil At Different Temperatures (Env89002.01)(Flumetsulam), DACO: 8.2.3.1
- 1143811 Effect Of Soil Properties On The Degradation And Sorption Of Xrd-498 (Gh-C 2243;87062)(Flumetsulam), DACO: 8.2.3.1
- 1143812 Anaerobic Aquatic Metabolism Of Xrd-498 (89080)(Flumetsulam), DACO: 8.2.3.1
- 1143813 Terrestrial Field Dissipation Of De-498 (Env87034/An; Env88075/An)(Flumetsulam), DACO: 8.3.2.3
- 1146697 Aged Leaching Of [14c] De-498 In A Canadian Field Soil (Env 92004;367-W-1)(Flumetsulam), DACO: 8.2.4.1
- 1146708 Aerobic Aquatic Metabolism Of [14c] De-498 In Canadian Pond Water And Sediment (Env 92005-1;368w-1;17753)(Flumetsulam), DACO: 8.2.3.1
- 1159712 Aerobic Aquatic Metabolism Of [14c]De-498 In Canadian Pond Water And Sediment: Results Through One-Year (Env92005.02;17753;368w-2;368w)(Flumetsulam), DACO: 8.2.3.1
- 1135655 Terrestrial Field Dissipation Of De-498 In Eastern Canada (Env 91038)(Xrm-5019 DACO: 8.3.2.3
- 1135656 Evaluation Of Flumetsulam Run Off For Southern Ontario (J.Wolt; 317-337-3484)(Xrm-5019), DACO: 8.3.3.3
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- 1143821 Xrd-498 Herbicide: A Dietary Lc50 Study With The Mallard (103-288)(Flumetsulam), DACO: 9.6.2.1
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- 1143842 Xrd-498 Herbicide An Acute Contact Toxicity With The Honey Bee (103-290a)(Flumetsulam), DACO: 9.2.4.1
- 1143843 De-498 Herbicide: Toxicity To The Earthworm Final Report (39445;Es-Dr-0238-5651-18b)(Flumetsulam), DACO: 9.2.3.1
- 1143854 Xrd-498 Herbicide: Evaluation Of The Toxicity To Daphnia Magna Straus Final Report (Es-2001;Es-Dr-0238-5651-3)(Flumetsulam), DACO: 9.3.1
- 1143867 Xrd-498 Herbicide: Evaluation Of The Toxicity To Rainbow Trout Final Report (Es-2002;Es-Dr-0238-5651-4)(Flumetsulam), DACO: 9.5.2.1
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- 1143872 Xrd-498 Herbicide: Evaluation Of The Toxicity To Fathead Minnow Final Report (Es-1099;Es-Dr-0238-5651-2)(Flumetsulam), DACO: 9.5.2.1
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- 1143875 Xrd-498 Herbicide: Acute Toxicity To Grass Shrimp Under Flow-Through Conditions (Es-2034;89309-0200-2130)(Flumetsulam), DACO: 9.4.1
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- 1146725 The Toxicity Of De-498 Herbicide To Lemna Gibba G3 (B460-13-4;Es-Dr-0238-5651-22)(Flumetsulam), DACO: 9.8.2
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| PMRA Document Number | Reference  |
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#### Unpublished Information

| PMRA Document Number | Reference  |
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| 1763866              | Unpublished Pesticide Science Fund water monitoring data from the Atlantic Region (complete raw dataset from 2003-2008). Environment Canada. DACO 8.6.   |
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| 2267501              | United States Geological Survey National Water Quality Assessment (NAWQA) program surface water, groundwater and treated water monitoring data for flumetsulam, downloaded November 26, 2012.<br><a href="http://infotrek.er.usgs.gov/apex/f?p=NAWQA:HOME:0">http://infotrek.er.usgs.gov/apex/f?p=NAWQA:HOME:0</a> DACO 8.6. |